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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,764	09/24/2003	Jeffrey M. Gross	4002-3424/PC889.00	4376

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Woodard, Emhardt, Moriarty, McNett & Henry LLP
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EXAMINER	-
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SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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08/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,764

Applicant(s)

GROSS ET AL.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 18-20, 27, 29, 30, 37-40, 43-46 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-17, 21-26, 28, 31-36, 41, 42, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/11/07, 6/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 6/15/07 have been fully considered. The objection to the drawings has been withdrawn.

Regarding the rejection of claim 49 under 35 U.S.C. 112, second paragraph, because *“positioning at least one member in the body extending from each of the first and second opposing sides partway toward the other opposing side” is not understood especially with respect to the elected embodiment. The language is identical to claim 30 which is withdrawn as indicated by applicant.* Applicant indicates that the language includes the subject matter shown in Figure 3, a non-elected species, thus has also been withdrawn and the rejection under 35 U.S.C. 112, second paragraph, has been withdrawn.

Regarding the rejection under 35 U.S.C. 112, first paragraph, wherein applicant's fusion device allows movement of the adjacent vertebrae, applicant more or less states there will be some micro-movement before fusion, the rejection has been withdrawn.

Regarding the rejections based on Germany (DE 20205016), applicant has submitted a declaration under 1.131 (as indicated on the lower left footnote) made by applicant's representative, Chris Brown. The declaration filed on 6/15/07 under 37 CFR 1.131 has been considered but is ineffective to overcome the Germany (DE 20205016) reference. ***MPEP 715 Swearing Back of Reference - Affidavit or Declaration Under 37 CFR 1.131 [R-3]*** teaches:

37 CFR 1.131 Affidavit or declaration of prior invention.

(a) When any claim of an application or a patent under reexamination is rejected, the **inventor** of the subject matter of the rejected claim, the

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owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.

Mr. Brown is not authorized to submit a declaration. Additionally, the evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Germany (DE 20205016) reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Applicant's exhibits do not support any of the claimed subject matter.

Regarding claim 2, chamfer means two surfaces meeting at an angle different from 90 degrees. It is unclear why the prior art reference is not showing this.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Germany (DE 20205016) wherein fixation device are used in combination with an intervertebral fusion device; see at least **applicant submitted** 2002/0107572. It further teaches oblique first and second surfaces, this is an official notice (MPEP 2144.03).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 10, 12, 16, 17, 26, 28, 35, 36, 47, 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Germany (DE 20205016).

Germany teaches:

1. A fusion implant for insertion between adjacent bony structures, the implant comprising:

a body 1 having opposing sides for contacting the adjacent bony structures; and
at least one member 3 positioned in the body, the member having a first end and a

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second end, the member having a tapered portion between the first and second ends.

Claim 6, "contained within the body" does not limit to not be exposed.

Claims 26 and 48, from side to side, the structural member 3 is only partway through.

Regarding claim 12, tricalcium phosphate or hydroxylapatite have been interpreted as bioglass. Also, see the state of the art (page 2 of the translation) teaching bone which within the scope of the teachings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-15, 21-25, 31-34, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Germany (DE 20205016).

Regarding claim 11, Germany teaches the body of the implant is preferably a polymer. However, it would have been obvious to one having ordinary skill in the art to have made the implant body from metal because of the well known characteristics including strength and biocompatibility and proven performance.

Germany teaches the fusion implant as described above, however, is silent regarding cancellous bone and cortical bone (at least claims 11-15 and 25). Germany teaches the use of synthetic materials in lieu of bone to avoid infection, etc. However, it

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is within the scope of the teachings and would have been obvious to one having ordinary skill in the art to have used bone (cortical and cancellous) to form the implant in any of the claimed configurations. Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make a bone fusion implant as claimed. Applicant has not disclosed that the use of bone provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the material taught by Germany or any of the materials taught by applicant.

Regarding at least claims 21-24 and 42, the use of a fixation device in combination with an intervertebral fusion device as claimed is well known in the art and would have been obvious to one having ordinary skill in the art to have used with the fusion device of Germany to better secure adjacent vertebrae.

Regarding at least claims 31 and 41, it is well known in the fusion art to have first and second surfaces which are oblique and would have been obvious to one having ordinary skill in the art to have done so with the fusion device of Germany to more closely match the oblique nature of the adjacent vertebrae.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

BRUCE SNOW
PRIMARY EXAMINER